APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Regulatory Affairs Specialist Phone: (650) 687-5874 Fax: (650) 687-4449
Date of Submission:	February 1, 2008
Device Trade Name:	TBD
Common Name:	Iontophoresis System
Device Classification:	Class III
Regulation Number:	21 CFR 890.5525
Classification Name:	Device, Iontophoresis, Specific Uses
Product Code:	EGJ
Predicate Devices:	1. Ionesthetizer (K884834) manufactured by Xomed 2. Model 6110C Otophor (K870272) manufactured by Life-Tech.
Device Description:	The Iontophoresis System (IPS) is a single-use device that employs electric current to transport drug solution, salts, or ions in the ear, including the tympanic membrane. The Iontophoresis System consists of 6 accessories: Control Unit, Ear Electrodes, Electrode Cable, Ear Plugs, Return Electrode, and Fill Nozzle.
Indications for Use:	The Iontophoresis System is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.
Technological Characteristics	The Iontophoresis System generates an electrical current in the ear. The electrical current transports drug solution, salts, or ions in the ear, including the tympanic membrane.
Performance Data	The Iontophoresis System met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The Iontophoresis System is substantially equivalent to the predicate devices as confirmed through relevant performance tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2008

Acclarent Inc.
c/o Ms. Keri Yen
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K073276
Trade Name: Iontophoresis System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device, Other Uses
Regulatory Class: Class III
Product Code: EGJ
Dated: February 1, 2008
Received: February 4, 2008

Dear Ms. Yen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K073276**

Trade Name: TBD

Common Name: Iontophoresis System

Indications For Use: The Iontophoresis System is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073276

(Posted November 13, 2003)